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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RONIT EISENBERG and TAMAR RAZ

Appeal 2009-014852
Application 10/009,809
Technology Center 1600

Before ERIC GRIMES, DONALD E. ADAMS, and STEPHEN WALSH,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON REQUEST FOR REHEARING¹

Appellants have requested rehearing of the decision entered April 26, 2010 (“Decision”), which affirmed the rejection of claims 63-70 and 72-78 under 35 U.S.C. § 103(a).

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

Appellants argue that we misunderstood their position in concluding that the evidence submitted did not show unpredictability regarding transport of proteins into cells (Req. Rhg. 1). Appellants argue that “[p]redictability of protein transport was never at issue. *Biological activity after transport* was the issue presented by appellants for review.” (*Id.*)

Appellants argue that, while it is predictable that a cell permeation peptide (CPP) will deliver a peptide to a cell (*id.* at 2), a fusion protein can be inactivated after it crosses the cell membrane (*id.* at 3). Appellants argue that

[a]s evidence of the unpredictability of biological activity after transport into a mast cell, appellants provided experimental evidence of the failure of various CPPs to retain the biological activity of Aridor’s peptide (p. 7) and two expert declarants provided three objective reasons why retention of activity was unpredictable once a protein is transported into a cell by any CPP (p. 8).

(*Id.*)

We are not persuaded that the Decision reflects a misunderstanding of the evidence and arguments presented on appeal. As noted in the Decision, Lin discloses that the KFGF signal peptide is effective in importing a “biologically active molecule,” including a peptide, into cells (Decision 4, FFs 1-5). Aridor discloses that its EC peptide (SEQ ID NO: 1) effectively inhibited histamine secretion when it was taken up by permeabilized mast cells (*id.* at 4-5, FFs 7, 8). These teachings support a reasonable expectation that importing Aridor’s peptide into mast cells by fusing it with Lin’s peptide, rather than by permeabilizing the mast cells, would also have the effect of inhibiting histamine secretion.

Appellants have not cited persuasive evidence supporting a contrary conclusion. Appellants point to the Specification's comparison of different CPPs fused to the peptide of SEQ ID NO: 1 (Req. Rhg. 3). The Specification, however, reports only that the fusion peptides that included the KFGF signal peptide inhibited histamine secretion from mast cells while the other four peptides "showed no inhibition" (Spec. 13: 23). Appellants have pointed to no evidence showing that the CPPs that were ineffective caused the attached peptides to be inactivated or sequestered after they entered the cell.

Appellants also point to the declarations of Ronit Sagi-Eisenberg and Ehud Razin as evidence that it was unpredictable whether Aridor's peptide would retain activity after entering a cell (Req. Rhg. 3). Dr. Sagi-Eisenberg and Dr. Razin provide several reasons "why fusing a CCP [sic, CPP] to a biologically active peptide might not result in observation of expected biological activity" (Sagi-Eisenberg Declaration 5, Razin Declaration 5).

The declarations do not support Appellants' conclusion because, while they provide some reasons why combining the peptides of Lin and Aridor "might not" have been successful, they provide no basis for concluding that those skilled in the art would have *reasonably expected* any of the listed factors to affect the specific combination relied on by the Examiner. That is, while the declarants speculate about why combining the references might not have succeeded, they provide no basis for concluding that those skilled in the art would have doubted the reasonable expectation of success.

In any event, Aridor provides evidence that its peptide is active when introduced into permeabilized mast cells, and Appellants have not pointed to

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persuasive evidence showing that those skilled in the art would have expected the same peptide to be inactive when introduced into the same cells via a different mechanism, such as Lin's KFGF signal peptide.

Appellants have not shown that we misapprehended or overlooked any issues of fact or law in the Decision. The request for rehearing is denied.

REHEARING DENIED

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834